

# Blue Goat Cyber Launches New Secure MedTech Product Design Consulting Service to Meet Growing Client Demand

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EINPresswire.com/ -- Blue Goat Cyber, a leader in medical device cybersecurity solutions, is proud to announce the expansion of its service portfolio with the introduction of Secure MedTech Product Design Consulting.

This new offering is tailored to assist medical device manufacturers in integrating robust cybersecurity measures at every stage of product design, ensuring compliance with regulatory requirements and enhancing patient safety.



## Meeting Market Demands with Expert Services



Cybersecurity should be embedded from the start to avoid costly redesigns, enhance patient safety, and confidently meet regulatory demands."

*Christian Espinosa, Blue Goat Cyber Founder and CEO*

The rapid evolution of connected medical technologies and increasing regulatory scrutiny have created a pressing need for comprehensive cybersecurity solutions in the MedTech industry. With its new service, Blue Goat Cyber addresses a critical gap in the market, helping manufacturers design secure products that meet FDA, EU MDR, and ISO standards while safeguarding patient data and device functionality.

Christian Espinosa, Founder and CEO of Blue Goat Cyber and author of Medical Device Cybersecurity: An In-Depth

Guide, emphasizes the importance of this service: "Cybersecurity should not be an afterthought in medical device development. By embedding security from the outset, manufacturers can

avoid costly redesigns, improve patient outcomes, and confidently navigate complex regulatory landscapes."

## Comprehensive Consulting for Secure Product Design

The Secure MedTech Product Design Consulting service focuses on integrating cybersecurity best practices into the entire product development lifecycle. Highlights of the service include:

- Threat Modeling and Risk Management: Leveraging advanced methodologies like STRIDE to identify potential vulnerabilities and mitigate risks proactively.
- Secure Software Development Practices: Aligning with frameworks like IEC 62304 to ensure software safety and reliability.
- Regulatory Compliance Support: Guiding manufacturers through FDA premarket submissions and global regulatory requirements, such as the EU MDR cybersecurity provisions outlined in Annex I.
- Lifecycle Security Integration: Embedding security into the Total Product Lifecycle (TPLC), from design to postmarket management.
- Third-Party Component Assessment: Addressing risks associated with Software of Unknown Provenance (SOUP) and ensuring secure integration of third-party systems.
- Documentation and Evidence Preparation: Preparing thorough technical files and cybersecurity documentation in line with FDA and international standards.

This service is grounded in the latest industry standards and guidelines, including FDA recommendations, NIST cybersecurity frameworks, and the Medical Device Coordination Group (MDCG) guidance on cybersecurity.

## Why Choose Blue Goat Cyber?

Blue Goat Cyber brings unparalleled expertise to the table. Under Christian Espinosa's leadership, the company has worked with leading medical device manufacturers to secure their products and navigate stringent regulatory processes.

Its unique approach combines technical excellence with deep regulatory knowledge, ensuring that clients meet compliance requirements and deliver products that inspire trust among patients and healthcare providers.

Blue Goat Cyber is launching this service to reinforce its commitment to advancing healthcare through secure innovation. The consulting team provides customized, actionable strategies that

align with each client's goals, balancing security, usability, and efficiency.

## Benefits for Medical Device Manufacturers

With the growing adoption of connected devices, medical device manufacturers face escalating threats and regulatory pressures. Blue Goat Cyber's new service offers tangible benefits, including:

- Accelerated Time-to-Market: By addressing cybersecurity during the design phase, manufacturers avoid delays caused by noncompliance or vulnerabilities.
- Enhanced Product Trustworthiness: Secure-by-design devices foster trust among patients, healthcare providers, and regulators.
- Reduced Liability: Robust cybersecurity minimizes breaches, recalls, and litigation risks.
- Regulatory Confidence: Expert guidance ensures alignment with FDA, EU MDR, and other international regulations, making global market access more attainable.

## A Vision for the Future of Secure Healthcare

Blue Goat Cyber's Secure MedTech Product Design Consulting is more than a service; it is a call to action for the MedTech industry.

As connected medical devices become increasingly central to patient care, the stakes have never been higher. Blue Goat Cyber is dedicated to empowering manufacturers to innovate confidently, knowing their devices are equipped to withstand today's cybersecurity challenges.

For more information about the Secure MedTech Product Design Consulting service, visit [Blue Goat Cyber's website](#) or contact their team at [info@bluegoatcyber.com](mailto:info@bluegoatcyber.com).

## About Blue Goat Cyber

Blue Goat Cyber specializes in cybersecurity solutions for the medical device industry, offering services ranging from FDA premarket submission support to postmarket management and incident response. Founded by Christian Espinosa, a seasoned cybersecurity expert, Blue Goat Cyber combines technical expertise with a deep understanding of regulatory landscapes to help clients achieve compliance and protect patient safety. For more information, visit <https://bluegoatcyber.com>.

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